UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,431	03/05/2001	Victoria Beck	00231-088002 / USSN 09/22	2545

7590 10/22/2002

J. PETER FASSE
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804

EXAMINER
CHISM, BILLY D

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/22/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/800,431	Applicant(s) BECK ET AL.	
	Examiner Billy D Chism	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *21-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 30-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The response filed 06 August 2002, Paper Number7, has been made of record. In response to the restriction requirement of 15 July 2002, Paper Number 6, Applicants elected Group I invention, claims 1-20 and 30-36, drawn to methods of treatment of neurological or immunological disorders using secretin, without traverse. The restriction requirement in now made FINAL.

The data provided in the specification on Page 1, lines 1-7, regarding Related Application, should be amended to recite that the present application is a continuation of Application No. 09/229/208, filed on January 13, 1999, now U.S. Patent No. 6,197.746, which claims benefit of U.S. Provisional Application No. 60/088,575.

Objections

Specification

1. The disclosure is objected to because of the following informalities: several pages within the specification have holes that make words illegible, and page 3 line 23 of specification is unclear wherein the words are not visible.

Appropriate correction is required.

Claims

Claim 20 is objected to for an informality in grammar. Claim 20 should read "produce" in place of "produces."

In claim 18, the word --selected—should be substituted for "select."

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for autism, does not reasonably provide enablement for treating a whole range of neurological or immunological disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation. The factors include:

1) the nature of the invention and breadth of the claims;

The claimed invention is drawn to a method for treatment of neurological or immunological disorders. However, there are no supporting data in the specification that the claimed invention treats any disorder other than that of autism. As discussed by Horvath *et al.* cited below (see sentence bridging columns1 and 2 on page 14, for example) that multiple secretin stimulations displayed no behavioral changes in non-autistic children. Furthermore, Horvath *et al.* does not teach that other neurological or immunological disorders can be treated with secretin. The claims are broader in scope than the specification, which is enabling only for the treatment of autism.

2) the predictability or unpredictability of the art;

The prior art does not provide grounds of adequate predictability or unpredictability regarding the use of secretin for neurological or immunological disorders other than autism.

3) the amount of direction or guidance presented;

The specification provides no direction regarding the use of the invention for disorders other than autism. Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). Given the teachings found in the prior art that therapeutic administration of secretin is unpredictable as a treatment for neurological or immunological disorders other than autism, detailed teachings regarding secretin therapy for other disorders are required to be present in the disclosure. Such teachings are absent. The specification discloses administration of secretin in two clinical cases of autism.

4) the presence or absence of working examples;

The working examples are limited to secretin therapy for treating autism. There is no disclosure of secretin treatment of any neurological or immunological disorders other than autism.

5) the quantity of experimentation necessary;

Given the teachings of unpredictability found in the art regarding treatment of neurological or immunological disorders other than autism and in the absence of disclosure in the specification of sufficient detail to overcome the teachings of unpredictability found in the art, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

6) the state of the prior art and relative skill of those skilled in the art; and,

The prior art does not adequately address the use of the methods for treatment of autism with secretin sufficiently enough to alleviate undue experimentation on one skilled in the art.

There is no evidence or indication that any other neurological or immunological disorder(s), other than autism, have been treated or are treatable with secretin.

4. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transdermal administration, does not reasonably provide enablement for transdermal administration of secretin by methods of acoustic waves. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation. The factors include:

7) the nature of the invention and breadth of the claims;

The claimed invention is drawn to a method for treatment of neurological or immunological disorders by transdermal administration of secretin by methods of acoustic waves. However, there are no supporting data in the specification that the claimed invention meets the requirements for delivering the appropriate pharmaceutically effective levels of secretin for treatment of autism within the specification's disclosed treatment regimen. The claim is broader in scope than the specification, which is enabling only for the treatment of autism through traditional transdermal methods.

8) the predictability or unpredictability of the art;

As the prior art is relatively new regarding the use of secretin for treatment of autism, the prior art does not provide grounds of adequate predictability or unpredictability regarding the use of acoustic waves for administration of secretin for treatment of autism.

9) the amount of direction or guidance presented;

The specification provides no direction regarding the use of the invention for use of acoustic waves for transdermal administration of secretin. Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). Given the teachings found in the prior art that therapeutic administration of secretin is by traditional means, orally or infusion, (Horvath *et al.* cited below) the use of acoustic waves for administration requires detailed teachings regarding secretin therapy by transdermal administration by methods of acoustic waves to be

present in the disclosure. Such teachings are absent. The specification discloses the possible use of acoustic waves for administration of secretin but offers no guidance.

10) the presence or absence of working examples;

There are no working examples of use of acoustic waves with transdermal administration of secretin. The disclosure only addresses examples where infusion and traditional transdermal methods are used. There is no disclosure of secretin treatment by means of acoustic waves.

11) the quantity of experimentation necessary;

Given the teachings of only traditional methods of transdermal administration found in the art regarding treatment and in the absence of disclosure in the specification of sufficient detail to overcome the teachings of traditional methods of transdermal application, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

12) the state of the prior art and relative skill of those skilled in the art; and,

The prior art does not adequately address the use acoustic waves for treatment of autism with secretin sufficiently enough to alleviate undue experimentation on one skilled in the art.

There is no evidence or indication that any method(s) other than the traditional approach of infusion or traditional transdermal administration would be sufficient in the delivery of a pharmaceutically adequate amounts of secretin for treatment of autism.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-20 and 30-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for the recitation of "disorders" wherein it is not clear what the metes and bounds are. What neurological and immunological disorders do the method steps treat? Although the specification refers to other disorders on page 3, lines 1-12, there is no indication in the specification by wording that these disorders are to be treated equally as autism, or that the referred to disorders are the neurological or immunological disorders to be treated with secretin as claimed.

Claims 2 and 30 are an improperly drawn claim as it depends from itself as claim 2. Claim 2 is indefinite for the recitation of the phrase "effective amount" wherein the phrase gives no indication as to what the effect is. The claim should clearly indicate that the secretin amount is effective in stimulating the pancreas.

Claims 4, 8, 32 and 36 are indefinite for recitation of the term "clinical unit" wherein neither the claims nor the specification clearly define or describe exactly what a clinical unit is in measurement terms.

In claims 6-9 and 34-35, the term "substance" renders the claim indefinite as to what is intended to be claimed, i.e., the claim's metes and bounds are unclear. The claims would be clearer through the deletion of the word "substance."

In claim 16, the term "spectrum disorders" renders the claim indefinite as to the coverage for the spectrum.

Claim 17 is indefinite for recitation of the phrase "sufficient to increase serotonin levels in the brain." This recitation is unclear as it is not understood if just any increase is sufficient, i.e. a small increase versus a considerable increase, for the treatment of the patient.

Claims 19 and 20 are indefinite wherein there are no steps for stimulating the duodenum causing the secretion of effective amounts of secretin. Furthermore, it is not clear if this is a method beyond the use of secretin as an administered treatment for autism. All methods are for the use of secretin for the treatment of autism, however, Applicants are unclear in claims 19-20 as to whether there are additional methods and agents to stimulate the release of endogenous secretin.

Claims 6, 10-11 and 34 are indefinite for reciting "portion of the skin" wherein it is not clear upon what area of the body the transdermal application is to be performed. Would an application to the leg or arm be as effective as application to the abdomen?

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-4, 7, 30-32 and 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 9 of U.S. Patent No. 6,020,310 ('310). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Although the claims are not word for word identical, they share the same metes and bounds. Claims 1-2 and 30 of present application are drawn to a method of treating the neurological disorder autism by stimulating the pancreas through administering secretin, however, the metes and bounds of the present claims 1-2 are the same as claim 1 of prior patent 6,020,310 wherein claim 1 was drawn to a method of treating the neurological disorder of autism by administration of secretin to patient. Furthermore, claims 3-4 have the same metes and bounds as claim 3 of the prior patent wherein administration of secretin is through an infusion of 2 clinical units per kilogram of body weight of patient. Claims 7 and 35 of present application have the same method step of using DMSO as the carrier for secretin as claim 9 of the prior patent. Therefore, the metes and bounds of the above mentioned claims are those of the prior patent and are statutory double patenting.

9. Claims 1-2, 5-10, 17, 30, and 35-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 5-10, 17, 30 and 33-36 of prior U.S. Patent No. 6,197,746. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Although the claims are not word for word identical, they share the same metes and bounds. Claims 1-2 and 30 drawn to method of treating neurological disorder autism with secretin as in claim 1 of prior patent. Claims 8 and 36 of present application drawn to treatment autism with up to 20 clinical units of secretin per kilogram of body weight of patient as in claim 2 of prior patent. Claims 5-7 and 33-35 drawn to a method of transdermal administration of secretin and a DMSO carrier wherein each component is administered separately for the treatment of neurological disorder autism as in claims 3-4 and 6-7 of prior application. Claim 9 of present application drawn to administration of secretin for treatment of neurological disorder autism through a gel or lotion as in claim 8 of prior application. Claim 10 of application drawn to the use of a patch for administration of secretin for treatment of neurological disorder autism as in claim 9 of prior application. Claim 17 drawn to method of administering secretin to yield increased serotonin levels as in claim 10 of prior patent for treatment of neurological disorder autism. Therefore, the metes and bounds of the above mentioned claims are those of the prior patent and are statutory double patenting.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1-4 and 30-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Horvath *et al.* 1998, J. of the Assoc. for Academic Minority Physicians, January, Vol. 9, No. 1:

9-15. Horvath *et al.* teaches the methods of infusion of 2 IU/kg of body weight of secretin for the purpose of stimulating pancreatic juice secretion in a patient with the neurological disorder autism (page 10). Since the method steps of Horvath *et al.* are those of the above mentioned claims in the present application, the method limitations of the claims are met by the method steps disclosed by Horvath *et al.*

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

***

B. Dell Chism
21 October 2002

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600